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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/524,228

02/09/2005

Alan John Johnstone

205139 (8830-308)

1559

7590

12/22/2008

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EXAMINER

NATNITHADHA, NAVIN

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

12/22/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/524,228	<b>Applicant(s)</b> JOHNSTONE, ALAN JOHN	
	<b>Examiner</b> NAVIN NATNITHITHADHA	<b>Art Unit</b> 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-9 and 11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-9 and 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 24 November 2008 has been entered.

### ***Response to Amendment***

2. According to the Amendment, filed 24 November 2008, the status of the claims is as follows:

Claims 1, 5, and 7 are currently amended;

Claim 2 is as originally filed;

Claims 3, 6, 8, 9, and 11 are previously presented; and

Claims 4, 10, and 12-23 are cancelled.

3. The objections to claim 7 is WITHDRAWN in view of the Amendment, filed 24 November 2008.

4. The 35 U.S.C. 112, second paragraph, rejection to claim 5 is withdrawn in view of the Amendment, filed 24 November 2008.

***Response to Arguments***

5. Applicant's arguments, see Remarks, p. 5, filed 24 November 2008, with respect to the rejection of claims 1-3, 8, 9, and 11 under 35 U.S.C. 102(b) as being anticipated by Dunn et al, U.S. Patent No. 5,766,432 A ("Dunn"), have been fully considered, but are moot in view of the new ground(s) of rejection.

6. Applicant's arguments, see Remarks, pp. 5-6, filed 24 November 2008, with respect to the rejection of claims 4-7 under 35 U.S.C. 103(a) as being unpatentable over Dunn in view of Khuri et al, U.S. Patent No. 6,567,679 B1 ("Khuri"), have been fully considered, but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-3, 5-9, and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Khuri.

Claims 1-3, 5-9, and 11: Khuri teaches the following:

a method of diagnosing a pathological condition of a patient's body tissue (see col. 1, ll. 36-44), the method comprising:

determining the presence or severity of ischemia in the tissue by inserting a pH sensor into the tissue, e.g. muscle (see col. 10, ll. 7-13),

directly measuring intracompartmental pH in the tissue (see fig. 2, and col. 4, l. 57, to col. 5, l. 4), and

using the intracompartmental pH measurement to diagnose the pathological condition ("The present invention relates to a method of using tissue pH measurements to diagnose ischemia and/or gauge the conduct of an operation by determining whether a site is ischemic. The current invention also provides methods by which tissue acidosis can be corrected once discovered.", see col. 1, ll. 36-44);

wherein the pH sensor consists of a single probe mounted on a catheter (see fig. 2, and col. 4, l. 57, to col. 5, l. 4).

In addition, Khuri teaches the catheter is inserted into the muscle through a cannula, which is inserted into skeletal muscle in an orientation that is generally parallel to the muscle fibres or is inserted into the muscle adjacent to a bone fracture site, but not communicating with the bone fracture site ("There are several methods of delivery of a pH electrode, used in pH-guided myocardial management, to a site of interest. The electrode can be delivered manually by the user. The electrode can also be delivered by a catheter through a percutaneous incision. The electrode can also be delivered by an endoscope, a colonoscope or a laparoscope to a site of interest. Thus, in a preferred embodiment of the invention, the method can be applied to other tissue measurements such as brain tissue, kidney tissue, musculo-cutaneous flaps or the small or large intestines. In another embodiment, the pH of transplanted organs, such as liver or

kidney, can be measured to assist in the diagnosis and/or treatment of rejection since acidosis is an early sign of rejection.”, see col. 2, ll. 5-18).

### ***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The other patents cited in the PTO-892 teach subject matter related to the Applicant's claims. The Examiner suggests reviewing these patents before responding to the present Office Action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to NAVIN NATNITHITHADHA whose telephone number is (571)272-4732. The examiner can normally be reached on Monday-Friday, 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Navin Natnithithadha/  
Patent Examiner, Art Unit 3735  
12/20/2008